REMARKS

Statement of Substance of Interview

Applicants appreciate the courtesy of a telephone interview between Examiner Javanmard, Examiner Wang, and the undersigned on April 27, 2010.

Proposed amendments to claim 1 were discussed. In this regard, Applicants explained that Kimura does not disclose the proposed feature of "due to nerve cell death by ischemic disorder" and so would not anticipate the proposed claims.

No agreement with respect to the claims was reached.

It is respectfully submitted that the present Statement of Substance of Interview complies with the requirements of 37 C.F.R. §§ 1.2 and 1.133 and MPEP § 713.04.

Remarks

Claim 1 has been amended to recite the species elected in the Response to Election of Species of October 29, 2009 and to recite that the subject ischemic nerve injury is "due to nerve cell death by ischemic disorder". Claims 2-7 have been canceled. Claims 11 and 12 are new.

Support is found, for example, on page 47, lines 11 to 19; page 48, lines 10 to 16; page 48, line 27 to page 49, line 3; page 10, lines 6 to 9; and page 33, lines 2 to 6.

No new matter has been introduced. Upon entry of the above amendments, which is respectfully requested, Claims 1 and 8-12 will be pending.

In the Office Action Summary of December 10, 2009, the Examiner acknowledged Applicants' claim for foreign priority under 35 U.S.C. § 119. However, the priority document

has not been indicated as received from the International Bureau. Applicants respectfully request acknowledgment of receipt in the next Office communication.

For the Examiner's reference, Applicants highlight the following with respect to amended claim 1:

Support for Compound SPF-3095-5 represented by formula [22] is found, for example, on page 50, line 11 to page 51, line 16 of the specification as filed.

Further, support for the feature of "due to nerve cell death by ischemic disorder" is found, for example, in the pharmacological data of Example 2. Specifically, the specification describes as follows:

"Furthermore, although no statistically significant difference was recognized, it was observed that *decrease of the thickness of the cell layer tends to be suppressed by pre-administration of SPF-3059-5, and cell death suppression effect on inner granular cell death was considered. In addition, cell death suppression effect by post-administration of SPF-3059-5 on inner granular cell death was shown statistically significantly*" (see page 47, lines 11 to 19).

"As a result of the above, it was shown that *SPF-3059-5 suppressed cell death of inner granular cells due to increased intra ocular pressure*. In addition, the inner plexus layer is a place where inner granular cells and gangliocytes form synapse and contains axons of gangliocyte and *protection effect on gangliocyte was therefore also thought of*" (see page 48, lines 10 to 16).

"From the result described above, it has been found in *ophthalmopathy that SPF-3059-5 is effective for diabetic retinopathy in which ischemic injury of inner granular cells is suspected* and glaucoma in which injury of gangliocyte is reported, etc." (see page 48, line 27 to page 49, line 3).

"The present inventors have found that *a compound having semaphorin inhibitory activity suppresses nerve cell death involved with ischemic injury and is useful as a therapeutic or preventive agent for ischemic nerve injury*" (see page 10, lines 6 to 9).

"The compounds of the present invention having semaphorin *inhibitory activity showed inhibitory effect on nerve cell death by ischemic disorder, and therefore, they can be used as a therapeutic agent or preventive agent for ischemic neurological diseases*" (see page 33, lines 2 to 6).

In view of the above, it is apparent that Compound SPF-3059-5 can effectively inhibit nerve cell death by ischemic disorder and therefore treat or prevent ischemic nerve injury due to nerve cell death by ischemic disorder.

Response to Rejection under 35 U.S.C. § 112

Claims 1, 2, 5, 6, and 8-10 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not enable the prevention of ischemic nerve injury.

The Examiner asserts that the specification does not provide information that would allow a skilled artisan to practice the claimed invention. In particular, the Examiner cites the *Wands* factors and reasons that, because there are allegedly no working examples showing how

to "prevent ischemic nerve injury totally, absolutely, or permanently" and such prevention is highly unpredictable, making and/or using the invention would require undue experimentation.

In response, Applicants traverse the Examiner's interpretation of the term "preventive". During examination, claims must be "given their broadest reasonable interpretation consistent with the specification" (MPEP 2111, citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005), emphasis added). Although the Examiner interprets "preventive" as meaning "preventing ischemic nerve injury totally, absolutely, or permanently", a skilled artisan would interpret the claim language in light of the examples disclosed in the specification. Contrary to the Examiner's assertion that Applicants provide no working examples, Applicants teach the effect of preventive agents in Examples 1 and 2 to suppress ischemic nerve injury. Examples 1 and 2 both teach pre-treatment of the respective test substances before IOP increase load. In each case, the effect of nerve injury is suppressed by the preventive agent.

Further, the specification teaches the preventive effect of the agent of amended claim 1 in Example 2. In particular, the pharmacological data of Example 2 demonstrate that decrease of the thickness of the cell layer tends to be suppressed by pre-administration of the claimed agent, and cell death suppression effect on inner granular cell death was considered.

Accordingly, Applicants respectfully submit that the present specification contains sufficient information regarding the subject matter of the claims, given their proper interpretation, as to enable one skilled in the relevant art to make and use the claimed invention without undue experimentation, and request that the Examiner reconsider and withdraw the above rejection.

Response to Rejection under 35 U.S.C. § 102

Claims 1, 2, 5, 6, and 8-10 are rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by WO 02/09756 to Kimura et al. The Examiner employs the English language equivalent US Patent 7,244,761 B2 ("Kimura").

The Examiner states that no patentable weight is given for the "intended use" of the claimed agent containing formula 1 as recited in Claims 1, 2, 5, 6, and 8-10, citing *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The features of Claims 8-10 appear to be disregarded as "intended use".

The Examiner cites, as meeting all the claimed features, chemical formula 27 of Kimura wherein R^1 and R^4 represent a carboxyl group and R^2 and R^5 represent a hydroxyl group.

In response, Applicants submit the following.

Kimura discloses a semaphorin inhibitor that exhibits *a nerve-regeneration promoting activity* and therefore can prevent or treat neuropathic disorders. Further, the nerve-regeneration promoting activity of Kimura is based on *the neurite outgrowth promoting activity or the growth cone collapse suppressing activity* of the semaphorin inhibitor. The therapy of neuropathic disorders based on neurite outgrowth promoting activity or growth cone collapse suppressing activity resides in the field of a regeneration therapy.

On the contrary, a characteristic of the present inventions resides in the new findings of the present inventors that Compound SPF-3059-5 can effectively inhibit nerve cell death by ischemic disorder. Amended claim 1 recites that the claimed agent is directed to "ischemic nerve

injury due to nerve cell death by ischemic disorder". Compound SPF-3059-5 therefore can treat or prevent ischemic nerve injury due to nerve cell death by ischemic disorder.

The inhibition of nerve cell death by ischemic disorder by Compound SPF-3059-5 protects nerve cells from death, and thus prevents a normal nerve circle network from being collapsed. Thus, the inhibition activity of Compound SPF-3059-5 on nerve cell death by ischemic disorder is fundamentally different from the nerve-regeneration promoting activity as taught by Kimura. Kimura does not disclose that Compound SPF-3059-5 can effectively inhibit nerve cell death by ischemic nerve injury due to nerve cell death by ischemic disorder.

Further, Kimura does not teach the features of new claims 11 and 12.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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